K073552

Laborie Medical Technologies Urodynamic System with Tetra Accessory
510(k) Summary
(per 21 CFR 807.92)

I. Applicant

Laborie Medical Technologies, Inc.
6415 Northwest Drive, Unit 10
Mississauga Ontario Canada L4V 1X1

MAR - 5 2008

Contact Person: Barbara Mornet, Regulatory Affairs Deputy
Tel: (802) 857-1300
Fax: (802) 878-1122
Email: bmornet@laborie.com

Date Prepared: December 14, 2007

II. Device Name

Proprietary Name:	Laborie Urodynamic System with Tetra Accessory
Common/ Usual Name:	Urodynamics Measurement System
Classification Name:	Device, cystometric, hydraulic, cystometer electrical recording
Regulation Number:	876.1620, 876.1800
Product Codes:	FEN, EXQ
Classification:	2
Classification Panel:	Gastroenterology/Urology

III. Predicate Device

The Laborie Urodynamic System with Tetra accessory is substantially equivalent to the Laborie Urodynamic Analyzer with 510(k) 931574 and all subsequent models that are now 510(k) exempt.

IV. Intended Use of the Device

Laborie Urodynamic systems are intended for Urodynamics testing. The traditional equipment performs standard tests including uroflowmeter, cystometry, micturition, electromyography and urethral pressure profiles. The accessory to our standard equipment, Tetra, uses near infrared spectroscopy, for non-invasive testing of bladder activity, aiding in the diagnosis of patients with lower urinary tract symptoms – that is patients who suffer from Urinary Incontinence.

Indications for Use

All Urodynamic equipment including the Laborie Urodynamic System with Tetra Accessory are for use under the direction of a licensed physical or health care professional in an office or hospital setting.

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V. Description of the Device

The complete device includes traditional Urodynamic system and the Tetra accessory. That is all the standard components, for uroflowmetry and pressure measurement, and the new non-invasive component the Tetra accessory to detect bladder activity.

VI. Summary of the Technical Characteristics

UDS-94	
Electrical Classification	Class I Equipment Type BF Applied Parts
Degree of Protection Against Ingress of Water	IPX0 Equipment
Mode of Operation	Continuous
Uroflow Rate	0 to 50 ml/s
Uroflow Volume	0 to 1100 ml
Pressure	-40 to 350 cm H2O
EMG†	-225 to 225 µV Frequency: 2 to 800 Hz
Pump	5 to 140 ml/min *
UPP Puller	0.5 to 3 mm/s
Infusion	0 to 1000 ml
T-Doc	-68 to 408 cmH2O
Data Conversion Rate	Min 10 Hz (min) up to 1000 Hz (optional up to 5000 Hz)
Tetra Accessory	
Wavelengths	785 nm, 808nm and 830nm
Energy Output	Up to 350 mJ
Type of Operation	Pulsed Only, 4 µsec
Class of Laser Products	Class I

* Maximum pump rate is limited by size of catheter used
† Sensitivity Range: +/- 1000 µV; High Pass: 800 Hz; Low Pass: 20 Hz

VII. Testing

Bench and clinical studies have confirmed the efficacy of the Laborie Urodynamic System with Tetra Accessory. Additional safety testing included electrical safety testing, laser safety testing and electromagnetic compatibility testing.

VIII. Safety & Effectiveness

The Laborie Urodynamic with Tetra Accessory is substantially equivalent to the Laborie Urodynamic Analyzer K931574 .There are no substantial differences except for the additional technology of the Tetra component for non invasive diagnostic testing. Both devices have the same intended use and the new technology does not introduce any issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAR - 5 2008

Ms. Barbara Mornet
Regulatory Affairs Deputy and Official Correspondent
Laborie Medical Technologies Corporation
400 Avenue D, Suite 10
WILLISTON VT 05495

Re: K073552
Trade/Device Name: Laborie Urodynamic System with Tetra Accessory
Regulation Number: 21 CFR 876.1620
Regulation Name: Urodynamics measurement system
Regulatory Class: II
Product Code: FEN and EXQ
Dated: December 14, 2007
Received: December 20, 2007

Dear Ms. Mornet:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Traditional 510(k) Urodynamic Tetra Accessory
Laborie Medical Technologies

5100 (k) Number (IF KNOWN): K073552 **Page 1 of 1**

DEVICE NAME: Urodynamic System Tetra Accessory

INDICATIONS FOR USE:

Laborie Urodynamic systems are intended for Urodynamic testing. The traditional equipment performs standard test including uroflometry, cystometry, micturition, electromyography and urethral pressure profiles. The accessory to our standard equipment, Tetra near infrared spectroscopy, uses non-invasive testing of bladder activity, aiding in the diagnosis of patients with lower urinary tract symptoms, that is patients who suffer from urinary incontinence

All Urodynamic equipment including the Laborie Urodynamic system with Tetra Accessory are for use under the direction of a licensed physician or health care professional in an office or hospital setting.

Prescription Use **X**

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K073552